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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application of: Lubenow et al.
Serial No.: 09/353,407
Filed: July 15, 1999
Entitled: Methods for Separating Particulate Substrates from Solution While Minimizing Particle Loss

ON APPEAL

ART UNIT: 1655
EXAMINER: A. Chakrabarti

Atty. Docket No.: QGN-004.0 US

Assistant Commissioner for Patents
Washington, D.C. 20231

REPLY BRIEF

Sir:

Pursuant to 37 CFR § 1.193(b)(1), Appellants submit this Reply Brief in response to the Examiner's Answer, mailed August 7, 2001 in the above-identified case. This Reply Brief is made to address and correct statements made in the Examiner's Answer which indicate a mischaracterization of Appellants' statement in their Brief On Appeal, misapplication of the patent law, misinterpretation of the references cited by the Examiner, mischaracterization of the state of the art, and a misunderstanding of Appellants' invention as embodied in the claims on appeal.

Appellants are filing this Reply Brief in triplicate within two months of the Examiner's Answer (Paper No. 18). No fee is believed to be required with this paper, however, the Commissioner is authorized by the undersigned to charge any additional fees required in connection with this Reply Brief and the papers submitted herewith to PTO Deposit Account No. 50-0268.

Appellants confirm that the Real Party in Interest and the state of Related Appeals and Interferences as reported in their Brief On Appeal (submitted July 20, 2001) remain the same.

The claims on appeal remain the same. Appellants have previously described the grouping of these claims on appeal (see, p. 8, Brief On Appeal).

The Examiner relies on one or a combination of more than one of the following documents as the basis for rejecting the appealed claims as anticipated or obvious under 35 U.S.C. §§ 102(e), 102(b), or 103(a):

1. United States Patent No. 5,942,391, issued Aug. 24, 1999 ("Zhang")
2. United States Patent No. 5,466,577, issued Nov. 14, 1995 ("Weisburg")
3. United States Patent No. 5,646,016, issued Jul. 8, 1997 ("McCoy")
4. United States Patent No. 5,798,442, issued Aug. 25, 1998 ("Gallant")
5. United States Patent No. 4,009,213, issued Feb. 22, 1977 ("Stein")

Appellants have previously reviewed each of the above references cited by the Examiner (see, pp. 4-7, Brief On Appeal), and they will not repeat their analysis here.

For reasons set forth in their Brief On Appeal, Appellants submit that a fair reading of each reference cited by the Examiner, either alone or in the combinations relied on by the Examiner, fails to disclose either (1) the problem addressed by Appellants' invention, i.e., loss of affinity particles during manipulations (e.g., collecting, washing, transferring) of such particles, or (2) Appellants' claimed method of contacting affinity particles with a detergent to prevent or reduce such loss of affinity particles during subsequent manipulation.

The Examiner has improperly characterized Appellants' statements regarding the references

In the Examiner's Answer, the Examiner stated:

"Appellant [sic] agrees that both Zhang and Weisburg references teach exactly the same structure and chemical composition of the claimed invention and may have enjoyed the benefit of practicing Appellants' claimed invention (Page 17 of the Appeal Brief) but the Appellant [sic] argues that the references are silent about the problem and benefit of the claimed invention."

See, p. 12, Examiner's Answer, emphasis added. Nowhere on this record have Appellants "agreed" that Zhang, Weisburg, any other reference of record, or any combination thereof relied on by the Examiner, teaches "exactly the same structure and chemical composition of the claimed invention" (see, emphasis in above quote). What Appellants stated in their Brief On Appeal was that:

"It may be that some of the examples in the primary references (Zhang and Weisburg) may have enjoyed the benefit of practicing Appellants' invention. It cannot be determined; the references are silent as to the characteristics of the affinity particles mentioned in passing in those references."

See, Appellants' Brief On Appeal, p.17, emphasis in original. The Examiner's distortion of Appellants' words notwithstanding, the patent law clearly recognizes that a patentable invention may have provided a benefit in an example of "accidental use, unrecognized by the art, without profit to the art, and therefore without legal significance as an anticipation." See, *In re Zierden*, 411 F.2d 1325, 1329, 162 USPQ 102, 105 (CCPA 1969). Hence, on this record, it is in the context of accidental use that the art may inadvertently have met the effect taught by Appellants in their application. Such inadvertent and accidental effects are not legally significant.

The Examiner has misunderstood and misapplied case law

The Examiner takes the position that the holding of *In re Zierden* is somehow abrogated by other case law relating not to the principle that accidental use is not anticipation but rather the principle that new benefits discovered in an old process do not make the process new again:

"Appellant argued that none of the references teach or suggest the problem of affinity particle loss during affinity separation procedure and the benefit of contacting affinity particles with detergent prior to the step of manipulating the particles to reduce particle loss compared to the affinity procedures in the absence of the detergent. Appellant cites *In re Zierden* for the proposition that a new use of a known process is patentable and the accidental use cannot anticipate the claimed invention. However, *In re Zierden* is not the final word in case law on this subject. In an old decision, the CCPA *In re Woodruff*, noted (1) 'it is a general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable. While the process encompassed by the claims are not entirely old, the rule is applicable here to the extent that the claims and the prior art overlap' See *In re Woodruff*, 16 U.S.P.Q. 2d (CCPA 1934) [sic]. (2) Another decision by the 5th circuit Board recites, 'When the process has been in well-established use, however, novelty is destroyed even though some of the benefits of the process are not recognized or appreciated', See *Bird Provision Co. V. Owens Country Sausage, Inc.* 197 U.S.P.Q. (CCPA 134) [sic].

"Finally two recent CAFC case laws make it clear, 'Where, as here, the result is a necessary consequence of what was deliberately intended, it is of no import that the article's authors did not appreciate the results', See *MEHLE/BIOPHILE V. Milgram*, 192 F.3d 1362 (CAFC 1999). 'Newly discovered results of known processes directed to the same purpose are not patentable because such results are inherent', See *Bristol-Myers Squibb V. Ben Venue Laboratories, Inc.*, 246 F. 3d 1368, (CAFC 2001)."

See, Examiner's Answer, pp. 12-13. However, as discussed below, the Examiner's rejections of the claims on appeal are not supported by the cases cited in the above quote.

In *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990), Woodruff claimed a process for inhibiting the growth of fungi on fresh leafy and head vegetables comprising maintaining such vegetables in an atmosphere of specific composition (e.g., carbon dioxide, oxygen, carbon monoxide, nitrogen) and temperature. However, all of the specified atmospheric components and temperature were included or overlapped with the ranges of the storage atmosphere specified in a patent to McGill, which, although never mentioning fungal growth, claimed a method of storing fresh leafy and head vegetables to maintain fresh appearance and, as explained in the specification, "to retard deterioration changes on storage, . . . and other enzymatic deterioration changes." See, *Woodruff*, 919 F.2d 1575, 1576, 16 USPQ2d 1934, 1935. Thus, Woodruff's disclosure actually was that the same prior art method of McGill for preventing deterioration of leafy and head vegetables was also effective against one other known cause of such deterioration, i.e., fungi. *Woodruff*, 919 F.2d 1575, 1577-1578, 16 USPQ2d 1934, 1936. It is in this context that the court cited the general principle and how it applied to Woodruff's method:

"It is a general rule that merely discovering and claiming a new benefit of an *old* process cannot render the process again patentable. *Verdegaal Bros., Inc. v. Union Oil Co. of Calif.*, 814 F.2d 628, 632-33, 2 USPQ2d 1051, 1054 (Fed. Cir.), cert. denied, 484 U.S. 827 (1987); *Bird Provision Co. v. Owens Country Sausage, Inc.*, 568 F.2d 369, 375, 197 USPQ 134, 139 (5th Cir. 1978). While the processes encompassed by the claims are not entirely *old*, the rule is applicable here to the extent that the claims and the prior art overlap.

"... In the present case, what Woodruff terms a 'new use' (preventing fungal growth) is at least generically encompassed by

the prior art purpose of preventing the deterioration of leafy and head vegetables."

Woodruff, 919 F.2d 1575, 1578, 16 USPQ2d 1934, 1936 (emphasis in original).

In contrast to the facts in *Woodruff*, Appellants have discovered how to prevent or minimize loss of affinity particles during manipulations, and no reference or combination of references cited by the Examiner discloses this problem either specifically or generically; and none of the references, alone or in combination, discloses Appellants' methods of contacting affinity particles with detergent for the purpose of solving the problem of affinity particle loss during manipulation. None of the Examiner's citations mentions the use of detergent in any other way than as an unexplained component of a reaction mixture. Accordingly, *Woodruff* is not applicable to the facts of Appellants' claimed methods.

Neither does the decision in *Woodruff* abrogate *Zierden*. In *Zierden*, the claims on appeal included methods for removing and preventing alluvium deposits (silt, mud, and /or organic wastes and other accumulations) in water systems, which comprised adding to such systems insoluble potassium metaphosphate and a solublizing agent. 411 F.2d 1325, 1326-1327, 162 USPQ 102, 103 (CCPA 1969). The Board of Appeals had affirmed rejections of the claimed methods as anticipated or obvious over a French patent claiming a method of removing calcium carbonate scale from industrial waters (such as heat exchange systems) comprising adding to such waters the same materials employed by appellant *Zierden*. *Id.* Thus, the scale prevention method of the French patent was also effective to remove and prevent alluvium accumulations in water systems. 411 F.2d 1325, 1327, 162 USPQ 102, 103. However, the French patent did not disclose the problem addressed by appellant *Zierden*'s claimed method, and the French patent did not teach or suggest the solution proposed by *Zierden*'s method: "We cannot find that the phenomenon appellant claims to have discovered would have been suggested to the art." 411 F.2d 1325, 1330, 162 USPQ 102, 105. Lacking such knowledge of the problem, the French patent did not anticipate or make obvious *Zierden*'s methods, despite, as appellant noted, the possibility of accidental use. 411 F.2d 1325, 1329, 162 USPQ 102, 105.

In another case cited in the Examiner's Answer, *Bird Provision Co. v. Owens Sausage, Inc.*, 568 F.2d 369, 196 USPQ 134 (Fed. Cir. 1978), an alleged infringer, Owens Sausage, Inc., challenged the validity of a patent held by Bird Provision Co. based on prior public use. The patent claimed methods for preparing pork sausage by a "hot-process" in which sausage is

prepared and packaged into air-impermeable containers in a sufficiently short time period before the meat temperature falls below 80°F. However, the evidence in the record showed that such a method of preparing pork sausage had been used on American farms for generations and, in particular, by two other sausage companies in the 1950's. See, *Bird Provision Co.*, 568 F.2d at 373. Bird Provision Co. attempted to argue for accidental use by alleging that others did not appreciate the benefit of increased shelf life of the packaged sausage. However, the argument of accidental use failed because:

"there is substantial evidence that the identical process claimed by the Bird Provision patent had previously been used for the same purpose: producing and preserving fresh pork sausage. *The prior users did not employ the process by chance.*"

See, *Bird Provision Co.*, 568 F.2d at 375 (emphasis added). In contrast to the situation in *Bird Provision Co.*, there is no evidence, no reference, and no combination of references relied on by the Examiner in this case that discloses either the problem of losing affinity particles during manipulations or Appellants' claimed methods of contacting the particles with detergent prior to manipulation to reduce or prevent particle loss during manipulation. Accordingly, *Bird Provision Co.* does not support the Examiner's rejections of the claims on appeal.

Similarly, the Examiner's reliance on *MEHL/Biophile International, Corp. v. Milgraum*, 192 F.3d 1362, 52 USPQ2d 1303 (Fed. Cir. 1999) is misplaced. In *MEHLE/Biophile*, an alleged infringer, Milgraum, challenged the validity of a patent held by MEHLE/Biophile International that claimed a method of hair depilation using a laser aligned substantially in a vertical position to destroy papillae at the base of a hair follicle that contains melanin-containing cells (melanosomes) that grow hair. However, the court agreed that such a method had been previously disclosed in a published research article describing destruction of melanosomes of hair follicles of test guinea pigs using an aligned laser. *MEHLE/Biophile*, 192 F.3d 1362, 1366, 52 USPQ2d 1303, 1306 (Fed. Cir. 1999). As the claim in the patent held by MEHLE/Biophile International was not limited to humans, the court concluded that the published research article anticipated the claim of the patent.

Again, the cited case involves the same method conducted for the same purpose in both a patent and in the prior art, the only discovery being new benefits (that were inherently occurring in the prior art). In the present appeal, the prior art only shows the same ingredients, not the

same process, or the same purpose, or the same teaching with respect to the steps of Appellants' method. Clearly, *MEHLE/Biophile* does not apply to Appellants' situation, where no reference or combination of references cited by the Examiner provides a disclosure of the claimed method steps or the reason for performing them.

The Examiner has also misunderstood and misapplied *Bristol-Myers Squibb Co. v. Ben Venue Laboratories, Inc.*, 246 F.3d 1368, 58 USPQ2d 1508 (Fed. Cir. 2001). In *Bristol-Myers*, Bristol-Myers Squibb sued Ben Venue Laboratories for infringement of two patents held by Bristol-Myers Squibb describing methods of treating a tumor patient by parenterally administering to the patient a specified amount of the anti-tumor drug paclitaxel over a three hour period. Ben Venue Laboratories alleged that the patents were invalid as anticipated by an article by Kris published more than one year prior to the filing of applications for the patents. The article by Kris described a phase I trial in which patients were treated by three-hour infusions of paclitaxel in amounts within the range specified in the patent claims. The issue was whether the Kris article was an anticipatory reference even though Kris observed no anti-tumor effect on the patients treated in his phase I study. The court concluded that Kris performed the same method for the same purpose as the methods claimed in the patents, i.e., methods for treating tumor patients with a specified amount of paclitaxel over a specified time period. See, *Bristol-Myers Squibb Co.*, 246 F.3d 1368, 1377, 58 USPQ2d 1508, 1514 (Fed. Cir. 2001). The court held that the article published by Kris was an anticipatory reference against the broadest claimed methods of the patents, even though in carrying out the same the method for the same purpose, Kris did not see the same anti-tumor result described in the patents. See, *Bristol-Myers Squibb Co.*, 246 F.3d at 1377-1380, 58 USPQ2d at 1514-1516 (Fed. Cir. 2001). It is within this context, that the court quoted the axiom, that which would infringe if later anticipates if prior. 246 F.3d at 1378, 58 USPQ2d at 1515 (Fed. Cir. 2001). However, as noted above, in Appellants' case, none of the references or combinations of references cited by the Examiner discloses Appellants' claimed methods for reducing or preventing loss of affinity particles during manipulations by contacting the affinity particles with detergent prior to manipulating the particles.

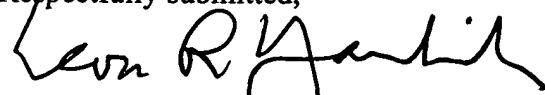
The above discussion of case law makes clear that the Examiner has misunderstood each of the cases cited in the Examiner's Answer and misapplied their legal conclusions to reject Appellants' claimed methods.

Finally, Appellants note the Examiner's view that Appellants have only analyzed the references individually to defeat the rejections of the claims as obvious over the specified combinations. However, Appellants submit that this record is replete with Appellants' careful and detailed analyses of each reference, alone and in the combinations specified by the Examiner. Each of the references and per force all combinations thereof cited by the Examiner fail to teach or suggest the very real problem of losing affinity particles during manipulations, and all combinations fail to solve the problem according to Appellants' claimed methods. In contrast, Appellants' have thoroughly described the problem and its solution, and have provided clear examples of practicing the invention (see, e.g., Examples 1-6 at pp. 20-29 of the specification).

The Examiner's Answer is fundamentally flawed by consistently citing text from court decisions out of context to provide a pretext for dismissing Appellants' sound legal arguments. As explained above, the cases cited and arguments made in the Examiner's Answer do not support or justify the final rejections.

For the reasons set forth above and in Appellants' main Brief On Appeal, Appellants respectfully submit that the Examiner has failed to make a *prima facie* case of obviousness or anticipation to reject the appealed claims. Accordingly, Appellants respectfully request that this Board reverse the final rejections and pass the appealed claims to allowance.

Respectfully submitted,



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